REMARKS

This Amendment is submitted in response to the Office Action dated March 2, 2004. In the Office Action, the Patent Office objected to the drawings under 37 CFR §1.84(p)(5) because the reference signs "23" is shown in FIG. 1 and are not mentioned in the description. Further, the Patent Office rejected Claims 1 and 2 under 35 U.S.C. §103(a) as being unpatentable over Roberts (U.S. Patent No. 6,124,521) in view of Yavitz (U.S. Patent No. 5,980,497) and further in view of Jensen et al. (U.S. Patent No. 6,592,888). Moreover, the Patent Office alternatively rejected Claims 1-22 under 35 U.S.C. §103(a) as being unpatentable over Roberts in view of Yavitz and further in view of Jensen et al.

With respect to the objections to the drawings, Applicant submits herewith corrections to FIG. 1 to remove the reference sign "23" as shown in the Replacement Drawings Sheets and as shown in red in the Annotated Sheets Showing Changes in the attached Appendix. Applicant submits that no new matter is being entered. Applicant further submits that the corrections to the figure overcome the objections by the Patent Office. Notice to that effect is requested.

By the present Amendment, Applicant amended Claims 1, 14 and 19 and added Claims 23-27. Applicant submits that no new matter is being entered by the addition of Claims 23-27. Further, Applicant submits that subject matter of Claims 23-27 is disclosed in U.S.

Provisional Application Serial No.: 60/272,362 upon which this application claims benefit. Applicant submit that the amendments to the drawings and the claims overcome the objections and the rejection by the Patent Office and places the application in condition for allowance. Notice to that effect is respectfully requested.

The Patent Office rejected Claims 1 and 2 under 35 U.S.C. §103(a) as being unpatentable over Roberts in view of Yavitz and further in view of Jensen et al. Applicant submits that the rejection has been overcome for the reasons that follow.

In the Office Action, the Patent Office alleges:

As regards Claim 1, Roberts substantially discloses the claimed invention. More specifically, Roberts discloses a semi-permeable film (20) having a top side and a bottom side, a tape border (12) having a top surface (16), a bottom surface (14), a first edge and a second edge wherein the semi-permeable film covers the top surface of the semi-permeable tape border, and an adhesive associated with the bottom surface of the semi-permeable tape border wherein the adhesive forms a barrier (col. 1, lines 54-59 and col. 3, lines 25-30). Roberts is silent as to the permeability of the tape, and fails to teach hydrocolloid silver adhesive.

Yavitz teaches that it is conventional to construct dressings from impermeable or semi-permeable cloth/fabric tape depending upon the intended use (col. 3, lines 24-42). Therefore, it would have been obvious to one having ordinary skill in the art, at the time the invention was made, to construct the cloth/fabric tape layer from semi-permeable material in order to allow the moisture from the skin of the user to evaporate.

As to the hydrocolloid silver adhesive, Jensen et al. teach that it is conventional in the art to provide wound dressings with adhesive material comprising both hydrocolloid material and silver because hydrocolloids are highly absorbent and silver is an anti-microbial

agent that kills bacteria (col. 3, line 26-col. 4, line 41).

In view of Jensen et al., it would have been obvious to one having ordinary skill in the art to modify Roberts by substituting the adhesive layer for a hydrocolloid adhesive because hydrocolloids are highly absorbent and silver is an anti-microbal agent that kills bacteria. Such a substitution requires only routine skill in the art.

On the contrary, Claim 1, as amended, requires a dressing having a semi-permeable tape border which has a top surface, a bottom surface, a first edge and a second edge wherein the semipermeable film covers the top surface of the semi-permeable tape border. Further, Claim 1 requires a hydrocolloid silver adhesive having a first side, a second side opposite the first side and a perimeter wherein the first side of the hydrocolloid silver adhesive is covered by the bottom surface of the semi-permeable Moreover, Claim 1 requires a window in the semitape border. permeable tape border and the hydrocolloid silver adhesive wherein the window in the semi-permeable tape border is aligned with the window in the hydrocolloid silver adhesive. Furthermore, Claim 1 requires the window extends from the second side of hydrocolloid silver adhesive to the semi-permeable tape border wherein the semi-permeable tape border extends outward with respect to the window beyond the perimeter of the hydrocolloid silver adhesive.

Roberts merely teaches "a self adherent window dressing having an absorbent pad dressing surrounding a semipermeable transparent

cover permitting visual inspection of an indwelling catheter access site; moisture vapor (gaseous) or fluid wicking around the site; and circumfluent absorption of fluid around the site." Further, Roberts teaches that "the fabric layer adhesive side 14 is coated with a hypoallergenic adhesive that is non-sensitizing" and that "the fabric tape layer 12 has an opening 18 therein to allow viewing of a catheter injection site, as illustrated in FIG. 1."

Contrary to the assertions of the Patent Office, Yavitz merely teaches a membrane shield for application over the eye of a wearer to retain moisture wherein the moisture shield includes a window that can be made of a transparent plastic. Further, Yavitz teaches that "a collar is connected to the perimeter of the window such that the collar extends outwardly from the window." Moreover, Yavitz teaches that "an adhesive layer, such as an adhesive gel, is applied to the collar to permit the moisture shield to be adhered to the wearer's face about the eye."

Jensen et al. merely teach an invention which relates to the field of dressings, and more particularly to the field of dressings for wounds, surgical cuts and other lesions to the human skin with anti-microbial properties. Further, Jensen et al. teach a dressing 10 which is applied over an area of skin 5 having a skin opening 50 and that the dressing 10 includes a dressing layer 20 and a backing layer 30.

None of Roberts, Yavitz or Jensen et al., taken singly or in combination, teach or suggest a dressing having a semi-permeable tape border which has a top surface, a bottom surface, a first edge and a second edge wherein the semi-permeable film covers the top surface of the semi-permeable tape border as required by Claim 1. Additionally, the Patent Office admits that "Roberts is silent as to the permeability of the tape, and fails to teach hydrocolloid silver adhesive." Further, nowhere does Jensen et al. disclose a semi-permeable tape border which has a top surface, a bottom surface, a perimeter, a first edge and a second edge wherein the semi-permeable film covers the top surface of the semi-permeable tape border.

Contrary to the assertions of the Patent Office, Yavitz merely teaches that a "membrane shield 10 includes a central window 12, a base 14, a collar 17 adjoining base 14 and an adhesive 18 for attaching membrane shield 10 to the face of a mammal, such as a human." Further, Yavitz teaches that "collar 17 can be integrally formed with base 14, or it can be a separate layer having a front surface 22 connected with base 14 and a back surface 24 for receiving adhesive 18." Still further, Yavitz teaches that the central window 12 preferably is made of a transparent material which should be impermeable to the passage of water vapor therethrough to ensure moisture does not escape from the wearer's eye. Therefore, none of Roberts, Yavitz or Jensen et al., taken

singly or in combination, teach or suggest a dressing having a semi-permeable tape border which has a top surface, a bottom surface, a first edge and a second edge wherein the semi-permeable film covers the top surface of the semi-permeable tape border as required by Claim 1.

Clearly, none of Roberts, Yavitz or Jensen et al., taken singly or in combination, teach or suggest a dressing having a hydrocolloid silver adhesive having a first side, a second side opposite the first side and a perimeter wherein the first side of the hydrocolloid silver adhesive is covered by the bottom surface of the semi-permeable tape border as required by Claim 1.

None of Roberts, Yavitz or Jensen et al., taken singly or in combination, teach or suggest a dressing having a window in the semi-permeable tape border and the hydrocolloid silver adhesive wherein the window in the semi-permeable tape border is aligned with the window in the hydrocolloid silver adhesive as required by Claim 1. Additionally, none of Roberts, Yavitz or Jensen et al., taken singly or in combination, teach or suggest a window which extends from the second side of the hydrocolloid silver adhesive to the semi-permeable tape border and further wherein the semi-permeable tape border extends outward with respect to the window beyond the perimeter of the hydrocolloid silver adhesive as required by Claim 1. Still further, the Patent Office admits that Roberts fails to teach hydrocolloid silver adhesive. Moreover,

nowhere does Yavitz disclose a hydrocolloid silver adhesive is connected to a bottom surface of a semi-permeable tape border wherein a perimeter of the hydrocolloid silver adhesive is located inside a perimeter of the semi-permeable tape border. Furthermore, Jensen et al. merely teaches that "the protective cover layer 30 may be provided as a protective covering for the dressing layer 10 on the side opposite the skin-contacting surface of the dressing 10."

Moreover, with respect to the rejection of Claim 1 under 35 U.S.C. §103(a), one of ordinary skill in the art at the time of Applicant's invention would never have been motivated to modify Roberts with Yavitz and/or Jensen et al. in the manner suggested by the Patent Office in formulating the rejection of the claim under 35 U.S.C. §103(a). It is submitted that the question under §103 is whether the art would suggest the claimed invention to one of ordinary skill in this art. In re Simon, 461 F.2d 1387, 174 USPQ 114 (CCPA 1972).

That elements, even distinguishing elements, are disclosed in the art is alone insufficient. It is common to find elements somewhere in the art. Moreover, most if not all elements perform their ordained and expected functions. The test is whether the invention as a whole, in light of the teachings of the references in their entireties, would have been obvious to one of ordinary skill in the art at the time the invention was made. <u>Connell v.</u>

<u>Sears, Roebuck & Co.</u>, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983).

Applicant submits that the Patent Office has merely located components of Applicant's claimed invention. However, that the art disclosed components of Applicant's claimed invention, either separately or used in other combinations, is insufficient. A teaching, suggestion, or incentive must exist to make the combination made by Applicant. Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1988). No such teaching, suggestion or incentive exists in Roberts, Yavitz or Jensen et al. to provide the novel features set forth in Applicant's claimed invention. Therefore, one of ordinary skill in the art would never have been motivated to modify Roberts with Yavitz and/or Jensen et al.

Still further, Applicant submits that the Patent Office is merely "piece-mealing" references together providing var, ious teachings and positively defined limitations of Applicant's dressing to deprecate the claimed invention. Of course, hindsight reconstruction of Applicant's invention is impermissible. Since no suggestion exists to modify Roberts with Yavitz and/or Jensen et al., the Patent Office cannot arbitrarily do so to reject the claim. Instead, a reason is required why one skilled in the art would be motivated to make the proposed combination of primary and secondary references. In re Nomiya, 184 USPQ 607 (CCPA 1975).

The court in *In re McLaughlin* stated "[T]here is no requirement that a motivation to make the modification be expressly articulated. The test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art." *In re McLaughlin*, 170 USPQ 209 (CCPA 1971).

In considering obviousness, the critical inquiry is whether something in the art as a whole suggests the desirability, and thus the obviousness, of making a combination. In re Newell, 891 F.2d 899, 901-02, 13 USPQ 2d 1248, 1250 (Fed. Cir. 19789). Since the Patent Office has failed to establish a prima facie case of obviousness in modifying Roberts with Yavitz and/or Jensen et al., the rejection of Claim 1 under 35 U.S.C. §103(a) is improper.

Furthermore, with the analysis of the deficiencies of Roberts, Yavitz and Jensen et al. in mind, as enumerated above, no reason or suggestion in the evidence of record exists why one of ordinary skill in the art at the time of Applicant's invention would have been led to modify Roberts with Yavitz and/or Jensen et al. in the manner suggested by the Patent Office in formulating the rejection under 35 U.S.C. §103(a). Even assuming that one having ordinary skill in the art could somehow have modified Roberts with Yavitz and/or Jensen et al., the references still lacks the critical features positively recited in Claim 1. Accordingly, the rejection

of Claim 1 under 35 U.S.C. §103(a) has been overcome and should be withdrawn. Notice to that effect is requested.

In view of the foregoing remarks and amendments, Applicant respectfully submits that the rejection of Claims 1 and 2 under 35 U.S.C. §103(a) has been overcome and should be withdrawn. Notice to that effect is requested.

With respect to the Patent Office alternative rejection of Claims 1-22 under 35 U.S.C. §103(a) as being unpatentable over Roberts in view of Yavitz and further in view of Jensen et al, Applicant respectfully submits that the rejections have been overcome for the reasons that follow.

In the Office Action, the Patent Office alleges:

As regards Claims 1, 2, 3, Roberts substantially discloses all features of the claims including a semipermeable film (20) having a top side and a bottom side, a tape border (12) having a top surface (16), a bottom surface (14), a first edge and a second edge wherein the semi-permeable film covers the top surface of the semipermerable tape border, an adhesive (14) associated with the bottom surface of the semi-permeable tape border wherein the hydrocolloid adhesive forms a barrier (col. 1, lines 54-59 and col. 3, lines 54-59), and an adhesive coating (22) on the bottom side of the semi-permeable film. Roberts additionally discloses an absorbent fiber layer (26) and a non-adherent porous film layer (30) secured thereto. The fiber layer provides moisture absorption and serves as a cushion, while the nonadherent porous film layer prevent the absorbent layer from sticking to the wound upon removal. Roberts fails to teach the permeability of the tape layer hydrocolloid silver adhesive.

Yavitz teaches that it is conventional to construct dressings from impermeable or semi-permeable cloth/fabric tape depending upon the intended use (col. 3, lines 24-42). Therefore, it would have been obvious to one having ordinary skill in the art, at the time the invention was

made, to construct the cloth/fabric tape layer from semipermeable material in order to allow the moisture from the skin of the user to evaporate.

As to the hydrocolloid silver adhesive, Jensen et al. teach that it is conventional in the art to provide wound dressings with hydrocolloid silver adhesive material because hydrocolloids are highly absorbent and silver is an anti-microbial agent that kills bacteria (col. 3, line 26 and col. 4, line 41).

It would have been obvious to one having ordinary skill in the art to modify Roberts by substituting the absorbent fiber layer, including the porous non-adherent film, for a hydrocolloid silver adhesive layer, since hydrocolloid silver adhesive material is highly absorbent, kills bacteria and/or prevents the growth thereof, and it does not adhere to wounds upon removal. This substitution provides the added benefit of an antimicrobial activity to the dressing.

As regards Claims 14-18, the claimed method of applying a dressing is accomplished by mere usage of the modified dressing of *Roberts* as discussed in the rejection of Claims 1 and 3-12.

As regards Claims 19-22, the claimed process of the manufacture of a dressing is accomplished by mere manufacturing of the modified dressing of *Roberts* as discussed in the rejection of Claims 1 and 3-12.

However, Claim 14, as amended, requires method for applying a dressing having a semi-permeable film, a semi-permeable tape border having an adhesive, a hydrocolloid silver adhesive and a first liner to a site on a patient having the placing the exposed portion of the dressing over a site of a patient. Further, Claim 14 requires the step of placing the exposed portion of the dressing over the site of the patient. Still further, Claim 14 requires that both the hydrocolloid silver adhesive and the semi-permeable tape border adhere to the patient wherein the hydrocolloid silver adhesive surrounds the site and further wherein the semi-permeable

film covers the site wherein the site is visible through the dressing.

Claim 19, as amended, requires a process for manufacture of a dressing having the step of providing a semi-permeable tape border manufactured with a bottom surface and a top surface opposite to the bottom side wherein the bottom side has an adhesive. Further, Claim 19 requires the step of cutting a window through the semi-permeable tape border and the adhesive layer wherein the window has a perimeter. Still further, Claim 19 requires the step of attaching a hydrocolloid silver adhesive to the adhesive layer of the semi-permeable tape border around the perimeter of the window wherein the semi-permeable tape border extends outward with respect to the window beyond the hydrocolloid silver adhesive. Moreover, Claim 19 requires forming a film on the top surface of the semi-permeable tape border wherein the film covers the window.

None of Roberts, Yavitz or Jensen et al., taken singly or in combination, teach or suggest a dressing having a semi-permeable tape border which has a top surface, a bottom surface, a perimeter, a first edge and a second edge wherein the semi-permeable film covers the top surface of the semi-permeable tape border as required by Claim 1. Roberts merely teaches that "absorbent fiber layer 26 provides circumfluent moisture absorption around the opening 18 keeping the viewing area clear and dry" and that "the absorbent fiber layer is a nonwoven fabric." Further, Roberts

teaches that "the non-adherent porous film layer 30 can be a polyethylene film or other suitable material that will not stick to the site upon removal." Nowhere do Yavitz and/or Jensen et al. disclose a dressing having a semi-permeable tape border which has a top surface, a bottom surface, a perimeter, a first edge and a second edge wherein the semi-permeable film covers the top surface of the semi-permeable tape border.

None of Roberts, Yavitz or Jensen et al., taken singly or in combination, teach or suggest a dressing having a hydrocolloid silver adhesive having a first side, a second side opposite to the first side and a perimeter wherein the first side of the hydrocolloid silver adhesive is covered by the bottom surface of the semi-permeable tape border as required by Claim 1. none of Roberts, Yavitz or Jensen et al., taken singly or in combination, teach or suggest a dressing having a window in the semi-permeable tape border and the hydrocolloid silver adhesive wherein the window in the semi-permeable tape border is aligned with the window in the hydrocolloid silver adhesive wherein the window extends from the second side of the hydrocolloid silver adhesive to the semi-permeable tape border and further wherein the semi-permeable tape border extends outward with respect to the window beyond the perimeter of the hydrocolloid silver adhesive as required by Cliam 1.

None of Roberts, Yavitz or Jensen et al., taken singly or in combination, teach or suggest a method for applying a dressing having a semi-permeable film, a semi-permeable tape border having an adhesive, a hydrocolloid silver adhesive and a first liner to a site on a patient as required by Claim 14. Moreover, none of Roberts, Yavitz or Jensen et al., taken singly or in combination, teach or suggest a method having the step of placing the exposed portion of the dressing over a site of a patient such that both the hydrocolloid silver adhesive and the semi-permeable tape border adhere to the patient wherein the hydrocolloid silver adhesive surrounds the site and further wherein the semi-permeable film covers the site wherein the site is visible through the dressing as required by Claim 14. Jensen et al. merely teach that "FIG. 1B shows the direction in which exudate is absorbed into the dressing layer 20 of the dressing 10 from the skin opening 50."

None of Roberts, Yavitz or Jensen et al., taken singly or in combination, teach or suggest a process for manufacture of a dressing having the step of providing a semi-permeable tape border manufactured with a bottom side and a top surface opposite to the bottom side wherein the bottom side has an adhesive as required by Claim 19. Further, one of Roberts, Yavitz or Jensen et al., taken singly or in combination, teach or suggest a process for manufacture of a dressing having the step of cutting a window through the semi-permeable tape border and the adhesive layer

wherein the window has a perimeter as required by Claim 19. Still further, none of Roberts, Yavitz or Jensen et al., taken singly or in combination, teach or suggest a process for manufacture of a dressing having the step of attaching a hydrocolloid silver adhesive to the adhesive on the bottom side of the semi-permeable tape border around the perimeter of the window wherein the semipermeable tape border extends outward with respect to the window beyond the hydrocolloid silver adhesive as required by Claim 19. Moreover, none of Roberts, Yavitz or Jensen et al., taken singly or in combination, teach or suggest a process for manufacture of a dressing having the step of forming a film on the top surface of the semi-permeable tape border wherein the film covers the window as required by Claim 19. On the contrary, Jensen et al. merely teach that "the protective cover layer 30 may be provided as a protective covering for the dressing layer 10 on the side opposite the skin-contacting surface of the dressing 10."

Moreover, with respect to the rejection of Claims 1, 14 and 19 under 35 U.S.C. §103(a), one of ordinary skill in the art at the time of Applicant's invention would never have been motivated to modify Roberts with Yavitz and/or Jensen et al. in the manner suggested by the Patent Office in formulating the rejection of the claims under 35 U.S.C. §103(a). It is submitted that the question under §103 is whether the art would suggest the claimed invention

to one of ordinary skill in this art. <u>In re Simon</u>, 461 F.2d 1387, 174 USPQ 114 (CCPA 1972).

That elements, even distinguishing elements, are disclosed in the art is alone insufficient. It is common to find elements somewhere in the art. Moreover, most if not all elements perform their ordained and expected functions. The test is whether the invention as a whole, in light of the teachings of the references in their entireties, would have been obvious to one of ordinary skill in the art at the time the invention was made. Connell v. Sears, Roebuck & Co., 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983).

Applicant submits that the Patent Office has merely located components of Applicant's claimed invention. However, that the art disclosed components of Applicant's claimed invention, either separately or used in other combinations, is insufficient. A teaching, suggestion, or incentive must exist to make the combination made by Applicant. Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1988). No such teaching, suggestion or incentive exists in Roberts, Yavitz or Jensen et al. to provide the novel features and steps set forth in Applicant's invention. Therefore, one of ordinary skill in the art would not have been motivated to modify Roberts with Yavitz and/or Jensen et al.

Still further, Applicant submits that the Patent Office is merely "piece-mealing" references together providing various

teachings and positively defined limitations of Applicant's dressing, method for applying a dressing and process for manufacture of a dressing to deprecate the claimed invention. Of course, hindsight reconstruction of Applicant's invention is impermissible. Since no suggestion exists to modify Roberts with Yavitz and Jensen et al., the Patent Office cannot arbitrarily do so to reject the claim. Instead, a reason is required why one skilled in the art would be motivated to make the proposed combination of primary and secondary references. In re Nomiya, 184 USPQ 607 (CCPA 1975).

The court in *In re McLaughlin* stated "[T]here is no requirement that a motivation to make the modification be expressly articulated. The test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art." *In re McLaughlin*, 170 USPQ 209 (CCPA 1971).

In considering obviousness, the critical inquiry is whether something in the art as a whole suggests the desirability, and thus the obviousness, of making a combination. In re Newell, 891 F.2d 899, 901-02, 13 USPQ 2d 1248, 1250 (Fed. Cir. 19789). Since the Patent Office has failed to establish a prima facie case of obviousness in modifying Roberts with Yavitz and Jensen et al., the rejection of Claims 1, 14 and 19 under 35 U.S.C. §103(a) is improper.

Furthermore, with the analysis of the deficiencies of Roberts, Yavitz and Jensen et al. in mind, as enumerated above, no reason or suggestion in the evidence of record exists why one of ordinary skill in the art at the time of Applicant's invention would have been led to modify Roberts with Yavitz and/or Jensen et al. in the manner suggested by the Patent Office in formulating the rejection under 35 U.S.C. §103(a). Even assuming that one having ordinary skill in the art could somehow have modified Roberts with Yavitz and/or Jensen et al., the references still lacks the critical features and steps positively recited in Claims 1, 14 and 19. Accordingly, the rejection of Claims 1, 14 and 19 under 35 U.S.C. §103(a) has been overcome and should be withdrawn. Notice to that effect is requested.

In view of the foregoing remarks and amendments, Applicant respectfully submits that the rejection of Claims 1-22 under 35 U.S.C. §103(a) has been overcome and should be withdrawn. Notice to that effect is requested.

Claims 2-13 depend from independent Claim 1; Claims 15-18 depend from independent Claim 14; and Claims 20-22 depend from independent Claim 19. These claims are further believed allowable over Roberts, Yavitz and Jensen et al. for the same reasons set forth with respect to their parent claims since each sets forth additional novel features and steps of Applicant's novel dressing,

method for applying a dressing and process for manufacture of a dressing, respectively.

In view of the foregoing remarks and arguments, Applicant respectfully submits that all of the claims in the application are in allowable form and that the application is in condition for allowance. If, however, any outstanding issues remain, Applicant urges the Patent Office to telephone Applicant's attorney so that the same may be resolved and the application expedited to issue. Applicant requests the Patent Office to indicate all claims as

allowable and to pass the application to issue.

espectfully submitted,

<u>(Reg. No. 35,018)</u>

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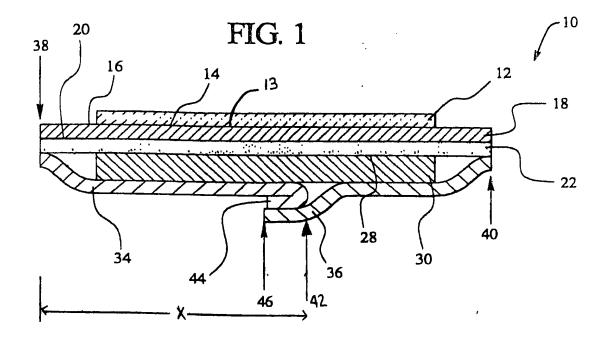
CERTIFICATE OF MAILING

I hereby certify that this Amendment and Appendix including Replacement Drawing Sheet and Annotated Sheet for FIG. 1 are being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Mail Stop Non-Fee Amendment, Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450

on April 21, 2004.

Brian M. Mattson (Reg / No. 35,018)

APPENDIX



Replacement Drawing Sheet